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(54) **Expandable intraluminal graft and apparatus for implanting an expandable intraluminal graft.**

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(56) References cited :
EP-A- 0 177 330
EP-A- 0 221 570
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Description

The invention relates to an expandable intraluminal graft or prosthesis for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease and to an apparatus for implanting expandable intraluminal grafts, as specified in the preambles of claims 1 and 5, respectively. Such grafts and apparatuses are known from document EP-A-0221570.

Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel.

Structures which have previously been used as intraluminal vascular grafts have included coiled stainless steel springs; helically wound coil springs manufactured from an expandable heat-sensitive material; and expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern. In general, the foregoing structures have one major disadvantage in common. Insofar as these structures must be delivered to the desired location within a given body passageway in a collapsed state, in order to pass through the body passageway, there is no effective control over the final, expanded configuration of each structure. For example, the expansion of a particular coiled spring-type graft is predetermined by the spring constant and modulus of elasticity of the particular material utilized to manufacture the coiled spring structure. These same factors predetermine the amount of expansion of collapsed stents formed of stainless steel wire in a zig-zag pattern. In the case of intraluminal grafts, or prostheses, formed of a heat sensitive material which expands upon heating, the amount of expansion is likewise predetermined by the heat expansion characteristics of the particular alloy utilized in the manufacture of the intraluminal graft.

Thus, once the foregoing types of intraluminal grafts are expanded at the desired location within a body passageway, such as within an artery or vein, the expanded size of the graft cannot be changed. If the diameter of the desired body passageway has been miscalculated, an undersized graft might not expand enough to contact the interior surface of the body passageway, so as to be secured thereto. It may then migrate away from the desired location within the body passageway. Likewise, an oversized graft might expand to such an extent that the spring force, or expansion force exerted by the graft upon the body passageway could cause rupturing of the body passageway. Further, the constant outwardly radiating force exerted upon the interior surface of the body passageway can cause erosion of the internal surface, or intima, of the artery or body passageway.

Another alternative to conventional vascular surgery has been percutaneous balloon dilation of elastic vascular stenoses, or blockages, through use of a catheter mounted angioplasty balloon. In this procedure, the angioplasty balloon is inflated within the stenosed vessel, or body passageway, in order to shear and disrupt the wall components of the vessel to obtain an enlarged lumen. With respect to arterial atherosclerotic lesions, the relatively incompressible plaque remains unaltered, while the more elastic medial and adventitial layers of the body passageway stretch around the plaque. This process produces dissection, or a splitting and tearing, of the body passageway wall layers, wherein the intima, or internal surface of the artery or body passageway, suffers fissuring. This dissection forms a "flap" of underlying tissue which may reduce the blood flow through the lumen, or block the lumen. Typically, the distending intraluminal pressure within the body passageway can hold the disrupted layer or flap, in place. If the intimal flap created by the balloon dilation procedure is not maintained in place against the expanded intima, the intimal flap can fold down into the lumen and close off the lumen, or may even become detached and enter the body passageway. When the intimal flap closes off the body passageway, immediate surgery is necessary to correct this problem.

Although the balloon dilation procedure is typically conducted in the catheterization lab of a hospital, because of the foregoing problem, it is always necessary to have a surgeon on call should the intimal flap block the blood vessel or body passageway. Further, because of the possibility of the intimal flap tearing away from the blood vessel and blocking the lumen, balloon dilations cannot be performed upon certain critical body passageways, such as the left main coronary artery, which leads into the heart. If an intimal flap formed by a balloon dilation procedure abruptly comes down and closes off a critical body passageway, such as the left main coronary artery, the patient could die before any surgical procedures could be performed.

Additional disadvantages associated with balloon dilation of elastic vascular stenoses is that many fail because of elastic recoil of the stenotic lesion. This usually occurs due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical characteristics of the area to be dilated. Thus, although the body passageway may initially be successfully expanded by a balloon dilation procedure, subsequent, early restenosis can occur due to the recoil of the body passageway wall which decreases

the size of the previously expanded lumen of the body passageway. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilation because the dilating forces are applied to the aortic wall rather than to the renal artery itself. Vascular stenoses caused by neointimal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters. Similar difficulties have been observed in angioplasties of graft-artery anastomotic strictures and postendarterectomy recurrent stenoses. Percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence which is believed due to the fibrotic nature of these lesions.

For repairing blood vessels narrowed or occluded by disease, or repairing other body passageways, the length of the body passageway which requires repair, as by the insertion of a tubular prosthetic graft, may present problems if the length of the required graft cannot negotiate the curves or bends of the body passageway through which the graft is passed by the catheter. In other words, in many instances, it is necessary to support a length of tissue within a body passageway by a graft, wherein the length of the required graft exceeds the length of a graft which can be readily delivered via a catheter to the desired location within the vascular system. Some grafts do not have the requisite ability to bend so as to negotiate the curves and bends present within the vascular system, particularly prostheses or grafts which are relatively rigid and resist bending with respect to their longitudinal axes.

Accordingly, prior to the development of the present invention, there has been no expandable intraluminal vascular graft for expanding the lumen of a body passageway, which: prevents recurrence of stenoses in the body passageway; can be utilized for critical body passageways, such as the left main coronary artery of a patient's heart; prevents recoil of the body passageway wall; allows the intraluminal graft to be expanded to a variable size to prevent migration of the graft away from the desired location and prevents rupturing and/or erosion of the body passageway by the expanded graft; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system. Therefore, the art has sought an expandable intraluminal vascular graft which: prevents recurrence of stenoses in the body passageway; is believed to be able to be utilized in critical body passageways, such as the left main coronary artery of the heart; prevents recoil of the body passageway; can be expanded to a variable size within the body passageway to prevent migration of the graft away from the desired location and to prevent rupturing and/or erosion of the body passageway by the expanded graft; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system.

SUMMARY OF THE INVENTION

In accordance with the invention, the foregoing advantages have been achieved by the present expandable intraluminal vascular graft or prosthesis. The present invention includes a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member; at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

A further feature of the present invention is that at least one connector member may be disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members. Another feature of the present invention is that the at least one connector member may be disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members. An additional feature of the present invention is that at least one connector member may be thin-walled, spiral member, coplanar with adjacent tubular members. The method of implanting the expandable intraluminal graft or prosthesis of the present invention comprises the steps of: disposing at least one connector member between adjacent prostheses to flexibly connect adjacent prostheses to each other; disposing a plurality of connected prostheses upon a catheter; inserting the prostheses and catheter within the body passageway by catheterization of the body passageway; and providing controllable expansion of at least one of the prostheses at a desired location within the body passageway by expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outwardly into contact with the body passageway, by deforming a portion of the at least one prostheses with a force in excess of the elastic limit of the portion of the at least one prostheses, to implant the

prostheses within the body passageway.

The portion of the catheter in contact with the prostheses may be collapsed, and the catheter removed from the body passageway. A catheter having an expandable, inflatable portion associated therewith may be utilized; and expansion of the prostheses and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

The slots of the tubular member according to the invention may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of each tubular member, whereby at least one elongate member is formed between adjacent slots.

In accordance with the invention, the foregoing advantages have also been achieved through the present apparatus for intraluminally reinforcing a body passageway, including a plurality of expandable and deformable, thin-walled tubular prostheses, each prosthesis having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axes of the tubular members prostheses, at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; and a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable and deformable tubular prostheses on the expandable, inflatable portion, whereby upon inflation of the expandable, inflatable portion of the catheter, the prostheses are expanded and deformed radially outwardly into contact with the body passageway. A further feature of the present invention is that the mounting and retaining means may comprise a retainer ring member disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable and deformable tubular prostheses.

The expandable intraluminal vascular graft and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts and balloon dilation techniques have the advantages of: preventing recurrence of stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; prevents erosion of the body passageway by the expanded graft; permits expansion of the graft to a variable size dependent upon conditions with the body passageway; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system.

BRIEF DESCRIPTION OF THE DRAWINGS:

In the drawings:

FIG. 1A is a perspective view of an expandable intraluminal vascular graft, or prosthesis for a body passageway, having a first diameter which permits delivery of the graft, or prosthesis, into a body passageway;

FIG. 1B is a perspective view of the graft, or prosthesis, of FIG. 1A, in its expanded configuration when disposed within a body passageway;

FIG. 2 is a cross-sectional view of the prosthesis taken along line 2-2 of FIG. 1B;

FIG. 3 is a cross-sectional view of an apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, illustrating a prosthesis, or intraluminal vascular graft, in the configuration shown in FIG. 1A;

FIG. 4 is a cross-sectional view of the apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, with the graft, or prosthesis, in the configurations shown in FIG. 1B;

FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon;

FIG. 7 is a perspective view of another embodiment of a graft or prosthesis in accordance with the present invention;

FIG. 8 is a cross-sectional view of the graft, taken along line 8-8 of FIG. 7.

FIG. 9 is a perspective view of the graft of FIG. 7, wherein the graft has been bent or articulated; and

FIG. 10 is a perspective view of the graft of FIG. 7, after the graft has been expanded and deformed.

DETAILED DESCRIPTION OF THE INVENTION:

In FIGS. 1A and 1B, an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway, 70 is illustrated. It should be understood that the terms "expandable intraluminal vascular graft" and "expandable prosthesis" are interchangeably used to some extent in describing the present invention, insofar as the methods, apparatus, and structures of the present invention may be utilized not only in connection with an expandable intraluminal vascular graft for expanding partially occluded segments of a blood vessel, or body passageway, but may also be utilized for many other purposes as an expandable prosthesis for many other types of body passageways. For example, expandable prostheses 70 may also be used for such purposes as: (1) sup-

portive graft placement within blocked arteries opened by transluminal recanalization, but which are likely to collapse in the absence of an internal support; (2) similar use following catheter passage through mediastinal and other veins occluded by inoperable cancers; (3) reinforcement of catheter created intrahepatic communications between portal and hepatic veins in patients suffering from portal hypertension; (4) supportive graft placement of narrowing of the esophagus, the intestine, the ureters, the urethra; and (5) supportive graft reinforcement of reopened and previously obstructed bile ducts. Accordingly, use of the term "prosthesis" encompasses the foregoing usages within various types of body passageways, and the use of the term "intraluminal vascular graft" encompasses use for expanding the lumen of a body passageway. Further, in this regard, the term "body passageway" encompasses any duct within the human body, such as those previously described, as well as any vein, artery, or blood vessel within the human vascular system.

Still with reference to FIGS. 1A and 1B, the expandable intraluminal vascular graft, or prosthesis, 70 is shown to generally comprise a tubular member 71 having first and second ends 72, 73 and a wall surface 74 disposed between the first and second ends 72, 73. Tubular member 71 has a first diameter, d, which, to be hereinafter described in greater detail, permits intraluminal delivery of the tubular member 71 into a body passageway 80 having a lumen 81 (FIG. 3). With reference to FIG. 1B, upon the application from the interior of the tubular member 71 of a radially, outwardly extending force, to be hereinafter described in greater detail tubular member 71 has a second, expanded diameter, d′, which second diameter d′ is variable in size and dependent upon the amount of force applied to deform the tubular member 71.

Tubular member 71, may be any suitable material which is compatible with the human body and the bodily fluids (not shown) with which the vascular graft, or prosthesis, 70 may come into contact. Tubular member 71 must also be made of a material which has the requisite strength and elasticity characteristics to permit the tubular member 71 to be expanded and deformed from the configuration shown in FIG. 1A to the configuration shown illustrated in FIG. 1B and further to permit the tubular member 71 to retain its expanded and deformed configuration with the enlarged diameter d′ shown in FIG. 1B and resist radial collapse. Suitable materials for the fabrication of tubular member 71 would include silver, tantalum, stainless steel, gold, titanium or any suitable plastic material having the requisite characteristics previously described.

Preferably, tubular member 71 is initially a thin-walled stainless steel tube having a uniform wall thickness, and a plurality of slots 82 are formed in the wall surface 74 of tubular member 71. As seen in FIG. 1A when tubular member 71 has the first diameter d, the slots 82 are disposed substantially parallel to the longitudinal axis of the tubular member 71. As seen in FIG. 1A, the slots 82 are preferably uniformly and circumferentially spaced from adjacent slots 82, as by connecting members 77, which connecting members 77 preferably have a length equal to the width of slots 82, as seen in FIG. 1A. Slots 82 are further uniformly spaced from adjacent slots 82 along the longitudinal axis of the tubular member 71, which spacing is preferably equal to the width of connecting members 77. Thus, the formation of slots 82 results in at least one elongate member 75 being formed between adjacent slots 82, elongate member 75 extending between the first and second ends, 72, 73 of tubular member 71, as seen in FIG. 1A.

Still with reference to FIG. 1A, each slot will have first and second ends with a connecting member 77 disposed at the first and second ends of slots 82. Preferably, the first and second ends of each slot 82 are disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Thus, connecting members 77, which are disposed at the first and second ends of each slot 82, and between elongate members 75, will in turn be disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Accordingly, slots 82 are preferably uniformly and circumferentially spaced from adjacent slots, and slots 82 adjacent to one another along the longitudinal axis of tubular member 71 are in a staggered relationship with one another. Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71. Although the graft, or prosthesis, 70 of FIGS. 1A and 1B is illustrated to have a length approximately equal to the length of two slots 82, it should be apparent that the length of the graft 70 could be made longer or shorter as desired.

The foregoing described construction of graft, or prosthesis, 70 permits graft, or prosthesis, 70 to be expanded uniformly, and outwardly, in a controlled manner into the configuration shown in FIG. 1B, upon the application of a suitable force from the interior of tubular member 71, as will be hereinafter described in greater detail. The expansion of tubular member 71 into the configuration shown in FIG. 1B is further uniform along the length of tubular member 71, not only because of the uniform spacing between slots 82, as previously described. but also because the thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79, is the same uniform thickness. As illustrated in FIG. 2. the uniform thickness of elongate

member 75 is shown, and the preferred cross-sectional configuration of elongate member 75, connecting member 77, and members 78, 79, is illustrated, which configuration is rectangular. It should of course be understood by those skilled in the art, that the cross-sectional configuration of the foregoing components of graft, or prosthesis, 70 could also be square, rectangular, or other cross-sectional configurations. As will be hereinafter described in greater detail, it is preferable that the outer surface 74 of graft, or prosthesis, 70, which would be in contact with the body passageway 80 FIG. 4, should be relatively smooth.

With reference to FIG. 1B, it is seen that after the graft, or prosthesis 70, has been expanded and deformed into the configuration of FIG. 1B, the slots 82 will assume a substantially hexagonal configuration when the tubular member 71 has the second, expanded diameter, d′, as shown in FIG. 1B. Such a hexagonal configuration will result when the slots 82 initially have a substantially rectangular configuration when the tubular member 71 has the first diameter, d, illustrated in FIG. 1A. It should be noted that were the width of slots 82 to be substantially reduced, whereby the length of connecting member 77 would approximate a single point intersection, the expansion of such a tubular member 71 would result in slots 82 assuming a configuration which would be substantially a parallelogram (not shown).

It should be noted that not only is tubular member 71 expanded from the configuration shown in FIG. 1A to achieve the configuration shown in FIG. 1B, but tubular member 71 is further "deformed" to achieve that configuration. By use of the term "deformed" is meant that the material from which graft, or prosthesis, 70 is manufactured is subjected to a force which is greater than the elastic limit of the material utilized to make tubular member 71. Accordingly, the force is sufficient to permanently bend elongate members 75 whereby segments of the elongate members 75 pivot about connecting members 77 and move in a circumferential direction as they pivot, whereby the diameter of the tubular member 71 increases from the first diameter, d, to the expanded diameter, d′, of FIG. 1B. The force to be applied to expand tubular member 71, which is applied in the manner which will be hereinafter described in greater detail, must thus be sufficient to not only expand tubular member 71, but also to deform elongate member 75, in the manner previously described, whereby the portions of the elongate members 75 which pivot about the ends of connecting members 77 do not "spring back" and assume their configuration shown in FIG. 1A, but rather retain the configuration thereof in FIG. 1B. Once graft, or prosthesis, 70 has been expanded and deformed into the configuration shown in FIG. 1B, graft, or prosthesis 70, will serve to prevent a body passageway from collapsing as will be hereinafter described in greater detail. It should be noted that when tubular member 71 has the first diameter, d, shown in FIG. 1A, or after tubular member 71 has been expanded and deformed into the second, expanded diameter, d′, of FIG. 1B, tubular member 71 does not exert any outward, radial force, in that tubular member 71 is not a "spring-like" or "self-expanding member", which would tend to exert an outwardly radial force.

With reference now to FIGS. 3 and 4, the apparatus of the present invention will be described in greater detail. Once again, it should be understood that the prosthesis and the apparatus of the present invention are useful not only for expanding the lumen of a body passageway, such as an artery, vein, or blood vessel of the human vascular system, but are also useful to perform the previously described procedures to intraluminally reinforce other body passageways or ducts, as previously described. Still with reference to FIGS. 3 and 4, an expandable intraluminal vascular graft, or prosthesis, 70, of the type described in connection with FIGS. 1A and 1B, is disposed or mounted upon a catheter 83. Catheter 83 has an expandable, inflatable portion 84 associated therewith. Catheter 83 includes means for mounting and retaining 85 the expandable intraluminal vascular graft, or prosthesis, 70 on the expandable, inflatable portion 84 of catheter 83. The mounting and retaining means 85 could comprise retainer ring members 86 disposed on the catheter 83 adjacent the expandable inflatable portion 84 of catheter 83; and a retainer ring member 86 is disposed adjacent each end 72, 73 of the expandable intraluminal vascular graft, or prosthesis, 70. Preferably, as seen in FIG. 3, retainer ring members are formed integral with catheter 83, and the retainer ring member 86 adjacent the leading tip 87 of catheter 83 slopes upwardly and away from catheter tip 87 in order to protect and retain graft or prosthesis, 70 as it is inserted into the lumen 81 of body passageway 80, as to be hereinafter described in greater detail. The remaining retainer ring member 86 as shown in FIG. 3, slopes downwardly away from tip 87 of catheter 83, to insure easy removal of catheter 83 from body passageway 80. After expandable intraluminal graft, or prosthesis, 70 has been disposed upon catheter 83, in the manner previously described, the graft, or prosthesis, 70 and catheter 83 are inserted within a body passageway 80 by catheterization of the body passageway 80 in a conventional manner.

In a conventional manner, the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway 80, whereat it is desired to expand the lumen 81 of body passageway 80 via intraluminal graft 70, or where it is desired to implant prosthesis 70. Fluoroscopy, and/or other conventional techniques may be utilized to insure that the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway.

Prosthesis, or graft, 70 is then controllably expanded and deformed by controllably expanding the expandable, inflatable portion 84 of catheter 83, whereby the prosthesis, or graft, 70 is expanded and deformed radially, outwardly into contact with the body passageway 80, as shown in FIG. 4. In this regard, the expandable, inflatable portion of catheter 83 may be a conventional angioplasty balloon 88. After the desired expansion and deformation of prosthesis, or graft, 70 has been accomplished, angioplasty balloon 88 may be collapsed, or deflated, and the catheter 83 may be removed in a conventional manner from body passageway 80. If desired, as seen in FIG. 3, catheter 83, having graft or prosthesis, 70 disposed thereon, may be initially encased in a conventional Teflon™ sheath 89, which is pulled away from prosthesis, or graft, 70, prior to expansion of the prosthesis, or graft, 70.

Still with reference to FIGS. 3 and 4, it should be noted that tubular member 71 of prosthesis, or graft, 70 initially has the first predetermined, collapsed diameter, d, as described in connection with FIG. 1A, in order to permit the insertion of the tubular member, 71 into the body passageway 80 as previously described. When it is desired to implant prosthesis 70 within a body passageway 80 for the purposes previously described, the prosthesis 70 is, controllably expanded and deformed to the second diameter, d′, and the second, expanded diameter, d′, is variable and determined by the internal diameter of the body passageway 80, as shown in FIG. 4, and by the amount of expansion of the inflatable portion 84 of catheter 83. Accordingly, the expanded and deformed prosthesis 70, upon deflation of angioplasty balloon 88 will not be able to migrate from the desired location within the body passageway 80, nor will the expansion of the prosthesis 70 be likely to cause a rupture of the body passageway 80. Furthermore, insofar as prosthesis, or graft, 70 is not a "spring-like" or "self-expanding member", the prosthesis is not consistently applying an outward, radial force against the interior surface of body passageway 80, in excess of that required to resist radial collapse of the body passageway 80. Thus, erosion of the interior surface, or intima, of the artery or body passageway is prevented.

When it is desired to use expandable intraluminal graft 70 to expand the lumen 81 of a body passageway 80 having an area of stenosis, the expansion of intraluminal vascular graft 70 by angioplasty balloon 88, allows controlled dilation of the stenotic area and, at the same time controlled expansion and deformation of the vascular graft 70, whereby vascular graft 70 prevents the body passageway 80 from collapsing and decreasing the size of the previously expanded lumen 81. Once again, the second, expanded diameter d′ of intraluminal vascular graft 70, as shown in FIG. 4, is variable and determined by the desired expanded internal diameter of body passageway 80. Thus, the expandable intraluminal graft 70 will not migrate away from the desired location within the body passageway 80 upon deflation of angioplasty balloon 88, nor will the expansion of intraluminal graft 70 likely cause a rupture of body passageway 80, nor any erosion as previously described. Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80. In the situation of utilizing graft 70 in the manner previously described to expand the lumen of a portion of a critical body passageway, such as the left main coronary artery, it is believed that the intimal flap will be unable to occlude the left main coronary artery of the heart and cause the death of the patient.

Because it is only necessary to inflate angioplasty balloon 88 one time in order to expand and deform graft 70, it is believed that a greater amount of endothelium, or inner layer of the intima, or inner surface of the body passageway, will be preserved, insofar as the extent of endothelial denudation during transluminal angioplasty is proportional to the balloon inflation time. Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through the openings or expanded slots 82 of graft 70. It is further believed that intact patches of endothelium within expanded slots 82 of graft 70 may result in a rapid, multicentricendothelialization pattern as shown by experimental studies.

With reference now to FIGS. 5 and 6, prostheses, or grafts, 70 of the type previously described in connection with FIGS. 1A and 1B are shown, and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert or biologically compatible coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon™, or other conventional biologically inert plastic materials. The coating 90 should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft, 70. Coating 90 may be further provided with a means for anchoring 91 (FIG. 6) the tubular member 71 to the body passageway 80. Anchoring means 91 may be comprised of a plurality of radially, outwardly extending projections 92 formed on the coating 90. As seen in FIG. 6, the radially outwardly extending projections 92 could comprise a plurality of ridges 93, or other types of radially, outwardly extending projections. Further, it may be desirable to have a plurality of openings 94 formed in coating 90, as shown in FIG. 5, whereby the fluid contained in body passageway 80 can be in direct contact with the dilated, or expanded, body passageway area. Examples of biologically compatible coatings 90

would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polylactides, and copolymers thereof. Such absorbable polymers could also contain various types of drugs, whereby as the coating 90 is absorbed, or dissolves, the drug would be slowly released into the body passageway 80.

Turning now to FIGS. 7-10, an expandable intraluminal vascular graft, or prosthesis, 70′ is shown for implantation in curved body passageways 80, or for use in the elongated sections of body passageway 80, when a prosthesis or a graft, 70′ is required which is longer than the graft, or prostheses, 70 of FIG. 1A. Identical reference numerals are used throughout FIGS. 7-10 for elements which are the same in design, construction, and operation, as those previously described in connection with FIGS. 1A-6, and primed reference numerals are used for elements which are similar in construction, design, and operation. as those previously described in connection with 1A-6.

As seen in FIG. 7, graft, or prosthesis, 70′ generally includes a plurality of prostheses, or grafts, 70 as described previously in connection with FIGS. 1A, 1B, and 2. Preferably, the length of each graft, or prosthesis, 70 is approximately the length of one slot 82; however, the length of each graft 70 could be approximately equal to the length of two slots 82, as illustrated in FIG. 1A. Disposed between adjacent tubular members, 71, or adjacent grafts, or prostheses, 70, is at least one connector member 100 to flexibly connect adjacent tubular members 71, or grafts, or prostheses, 70. Connector member, or members, 100 are preferably formed of the same material as grafts 70, as previously described, and connector members 100 may be formed integrally between adjacent grafts 70, or tubular members 71, as shown in FIG. 7. As seen in FIG. 8, the cross-sectional configuration of connector member, or members, 100, along the longitudinal axis of graft, or prosthesis 70′, is the same, in that connector member, or members, 100 have the same uniform wall thickness of elongate members 75. Of course, it should be readily apparent to one of ordinary skill in the art, that the thickness of connector members 100 could alternatively be smaller than that of elongate members 75; however, it is preferable that the outer circumferential surface 101 of connector members 100 lies in the same plane formed by the wall surface 74 of grafts, or prostheses 70, as seen in FIG. 8.

Still with reference to FIGS. 7-8, connector members 100 are preferably disposed in a non-parallel relationship with respect to the longitudinal axis of adjacent grafts, or prostheses, 70. Further, it is preferable that the at least one connector member 100 is formed as a thin-walled spiral member 102 which is coplanar with the outer wall surface 74 of the adjacent tubular members 71, or adjacent grafts, or prostheses, 70. It should be noted that although graft, or prosthesis, 70′ is illustrated as including three grafts, or prostheses, 70 flexibly connected to one another by connector members 100, as few as two grafts 70 could be connected to form graft, or prosthesis, 70′. Furthermore, many grafts 70 could be flexibly connected by connector members 100 as are desired to form graft, or prosthesis, 70′.

The delivery and expansion of graft, or prosthesis, 70′ is the same as that previously described in connection with FIGS. 1A, 1B, and 3-4. The length of the expandable, inflatable portion 84 of catheter 83 would be sized to conform with the length of the graft, or prosthesis, 70′, as should be readily apparent to one of ordinary skill in the art. Except for the length of the expandable, inflatable portion 84, catheter 83, the method of delivery of graft, or prosthesis, 70′ and its subsequent, controllable expansion and deformation are the same as previously described.

With reference to FIG. 9, the prosthesis 70′ is illustrated in the configuration it would assume when being delivered to the desired location within the body passageway 80, and the graft, or prosthesis, 70′ is disposed upon catheter 83 and is passing through a curved portion of body passageway 80, such as an arterial bend. For clarity, catheter 83 is not shown in FIG. 9, since the flexibility of such catheters 83 is well known in the art. As seen in FIG. 9, because of the disposition of flexible connector members 100 between adjacent tubular members 71, or grafts, or prostheses, 70, graft, or prosthesis, 70′ is able to flexibly bend, or articulate, with respect to the longitudinal axis of graft, or prosthesis, 70′, so as to be able to negotiate the curves or bends found in body passageways 80. As seen in FIG. 9, as graft, or prosthesis, 70′ bends, or articulates about the longitudinal axis of graft 70′, the spacing between tubular members 71 increases, or expands, about the outer side of the curve, or bend, 103; and the spacing decreases, or is compressed, on the inner side of the curve, or bend, 104. Likewise, spiral connector members 102 adjacent the outer side of the curve 103 flexibly and resiliently stretch to permit the expansion of the spacing thereat; and the spiral connector members 102 adjacent the inner side of the curve, 104 flexibly and resiliently compress to permit the decrease in the spacing between tubular members 71 on the inner side of curve 104. It should be noted that connector members 100 permit the bending, or articulation, of adjacent tubular members 71 in any direction about the longitudinal axis of graft, or prosthesis, 70′.

Turning now to FIG. 10, graft, or prosthesis, 70′ is illustrated in its expanded, and deformed configuration, similar to that illustrated in FIG. 1B. It should be noted that should it be desired to implant graft, or prosthesis, 70′ on a curved portion of a body passageway 80, such implantation and expansion would be permitted by the connector members 100. It should

also be noted that prostheses, or grafts, 70 could be flexibly connected to one another to form a graft, or prosthesis, 70′ wherein such grafts, or prostheses, 70 are formed as wire mesh tubes of the type illustrated in Applicant's co-pending Application EP-A- 0221570.

It is to be understood that the invention is not to be limited to the exact details of construction, operation, exact materials, or embodiments shown and described, as obvious modifications and equivalents will be apparent to one skilled in the art. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

Claims

1. An expandable intraluminal vascular graft, or prosthesis (70) comprising:

a least one thin-walled tubular member (71) having first and second ends (72, 73) and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots (82) formed therein, the slots (82) being disposed substantially parallel to the longitudinal axis of said tubular member (71);

the tubular member (71) having a first diameter which permits intraluminal delivery of the tubular members into a body passageway (80) having a lumen (81); and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member (71) whereby the tubular member (71) may be expanded and deformed to expand the lumen of the body passageway,

characterised in that the vascular graft or prosthesis (70) comprises a plurality tubular members (71) and at least one connector member (100) being disposed between adjacent tubular members to flexibly connect adjacent tubular members.

2. The expandable intraluminal graft or prosthesis of claim 1, **characterised in that** at least one connector member (100) is disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members (71).

3. The expandable intraluminal graft of prosthesis of claim 1 or 2, **characterised in that** at least one connector member (100) is disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members (71).

4. The expandable intraluminal graft or prosthesis of one of claims 1 to 3 **characterised in that** at least one connector member (100) is a thin-walled, spiral member, coplanar with adjacent tubular members (71).

5. An apparatus far intraluminally reinforcing or expanding the luminen of a body passageway, comprising a prosthesis or vascular graft (70) having at least one expandable and deformable, thin-walled tubular member (71) having first and second ends (72, 73) and a wall surface disposed between the first and second ends (72, 73), the wall surface having a plurality of slots (82) formed therein, the slots (82) being disposed substantially parallel to the longitudinal axis of the tubular members (71) a catheter (83), having an expandable, inflatable portion (84) associated therewith and including means for mounting and retaining the expandable, thin-walled tubular prosthesis or vascular graft (70) on the expandable, inflatable portion (84), whereby upon inflation of the expandable, inflatable portion of the catheter (83) the member (71) is expanded and deformed radially outwardly into contact with the body passageway (80) **characterised in that** the apparatus comprises a plurality of thin-walled tubular members (71) and at least one connector member (100) being disposed between adjacent tubular members (71) to flexibly connect adjacent tubular members (71).

6. The apparatus of claim 5, **characterised in that** the mounting and retaining means comprises retainer ring members (86) disposed on the catheter (83) adjacent the expandable, inflatable portion (84) and adjacent the ends of the expandable, tubular prostheses (70).

Patentansprüche

1. Aufweitbares intraluminales vaskuläres Gewebe oder Prothese (70) mit

zumindest einem dünnwandigen rohrförmigen Teil (71) mit ersten und zweiten Enden (72, 73) und einer zwischen dem ersten und dem zweiten Ende angeordneten Wandfläche, die eine im wesentlichen gleichförmige Dicke und mehrere Schlitze (82) aufweist, die im wesentlichen parallel zu der Längsachse des rohrförmigen Teiles (71) ausgerichtet sind,

wobei das rohrförmige Teil (71) einen ersten Durchmesser aufweisen kann, der den intraluminalen Transport des rohrförmigen Teils in einen ein Lumen (81) aufweisenden Körperdurchgang (80) ermöglicht, und

wobei das rohrförmige Teil einen zweiten, aufgeweiteten und deformierten Durchmesser aufweisen kann, nachdem vom Inneren des rohrförmigen Teils aus eine radial nach außen gerichtete Kraft aufgebracht ist, wobei der zweite Durchmesser variabel ist und vom Betrag der auf das rohrförmige Teil (71) ausgeübten Kraft abhängt, wodurch das rohrförmige Teil (71) aufgeweitet und deformiert wird, um das Lumen des Körperdurchgangs aufzuweiten,

dadurch gekennzeichnet, daß das vaskuläre Gewebe oder die vaskuläre Prothese (70) mehrere rohrförmige Teile (71) und zumindest ein Verbin-

dungsteil (100) aufweist, welches zwischen aneinander angrenzenden rohrförmigen Teilen angeordnet ist, um aneinander angrenzende rohrförmige Teile biegbar miteinander zu verbinden.

2. Auweitbares intraluminales Gewebe oder Prothese nach Anspruch 1, **dadurch gekennzeichnet**, daß zumindest ein Verbindungsteil (100) in einer nicht-parallelen Anordnung bezüglich der Längsachse der rohrförmigen Teile (71) angeordnet ist.

3. Aufweitbares intraluminales Gewebe oder Prothese nach Anspruch 1 oder 2, **dadurch gekennzeichnet**, daß zumindest ein Verbindungsteil (100) coplanar zu jedem rohrförmigen Teil und nicht parallel zur Längsachse der rohrförmigen Teile (71) angeordnet ist.

4. Aufweitbares intraluminales Gewebe oder Prothese nach einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet**, daß zumindest ein Verbindungsteil (100) ein dünnwandiges Spiralteil ist, das coplanar zu den angrenzenden rohrförmigen Teilen (71) angeordnet ist.

5. Gerät zum intraluminalen Verstärken oder Expandieren des Lumens eines Körperdurchgangs, umfassend eine Prothese oder ein vaskuläres Gewebe (70) mit zumindest einem expandierbaren und deformierbaren, dünnwandigen rohrförmigen Teil (71) mit ersten und zweiten Enden (72, 73) und einer Wandfläche, die zwischen dem ersten und dem zweiten Ende (70, 73) angeordnet ist, wobei die Wandfläche mehrere darin ausgeformte Schlitze (82) aufweist, die im wesentlichen parallel zur Längsachse der rohrförmigen Teile (71) angeordnet sind, einen Katheter (83) mit einem damit verbundenen aufweitbaren, aufblasbaren Abschnitt (84) und mit einer Einrichtung zum Festhalten der aufweitbaren, dünnwandigen rohrförmigen Prothese bzw. vaskulären Gewebes (70) auf dem aufweitbaren, aufblasbaren Abschnitt (84), wodurch nach Aufblasen des aufweitbaren, aufblasbaren Abschnitts des Katheters (83) das Teil (71) aufgeweitet und radial nach außen bis in Berührung mit dem Körperdurchgang (80) deformiert wird, **dadurch gekennzeichnet**, daß das Gerät mehrere dünnwandige rohrförmige Teile (71) und zumindest ein Verbindungsteil (100) umfaßt, das zwischen aneinander angrenzenden rohrförmigen Teilen (71) angeordnet ist, um aneinander angrenzende rohrförmige Teile (71) biegbar miteinander zu verbinden.

6. Gerät nach Anspruch 5, **dadurch gekennzeichnet**, daß die Befestigungs- und Halteeinrichtung Halteringteile (86) umfaßt, die auf dem Katheter (83) angrenzend an den aufweitbaren aufblasbaren Abschnitt (84) und angrenzend an die Enden der aufweitbaren, rohrförmigen Prothesen (70) angeordnet sind.

Revendications

1. Greffe ou prothèse vasculaire expansible intraluminaire, comprenant :

au moins un organe tubulaire à paroi mince (71), comportant des première et seconde extrémités (72,73) et une surface de paroi, disposée entre les première et seconde extrémités, la surface de paroi présentant une épaisseur sensiblement uniforme et une pluralité de fentes (82) formées en son sein, les fentes (82) étant disposées sensiblement parallèlement à l'axe longitudinal dudit organe tubulaire (71);

l'organe tubulaire (71) présentant un premier diamètre qui permet une amenée intraluminaire des organes tubulaires dans une voie de passage dans le corps (80) qui comporte un lumen (81); et

l'organe tubulaire (71) présentant un deuxième diamètre, à l'état expansé et déformé, lors de l'application, depuis l'intérieur de l'organe tubulaire, d'une force radiale orientée vers l'extérieur, ce second diamètre étant variable et dépendant de l'ampleur de la force appliquée à l'organe tubulaire (71), de manière que ce dernier puisse être expansé et déformé pour dilater le lumen de la voie de passage dans le corps,

caractérisée en ce que la greffe ou prothèse vasculaire (70) comprend une pluralité d'organes tubulaires (71) et au moins un connecteur (100) étant disposé entre des organes tubulaires adjacents, pour relier de façon flexible des organes tubulaires adjacents.

2. Greffe ou prothèse expansible intraluminaire selon la revendication 1, caractérisée en ce qu'au moins un connecteur (100) est disposé en une relation non parallèle par rapport à l'axe longitudinal des organes tubulaires (71).

3. Greffe ou prothèse expansible intraluminaire selon la revendication 1 ou 2, caractérisée en ce qu'au moins un connecteur (100) est disposé coplanaire avec chaque organe tubulaire et non parallèlement par rapport à l'axe longitudinal des organes tubulaires (71).

4. Greffe ou prothèse expansible intraluminaire selon l'une des revendications 1 à 3, caractérisée en ce qu'au moins un connecteur (100) est un organe à paroi mince, spiral, coplanaire les organes tubulaires (71) adjacents.

5. Dispositif, pour renforcer ou expanser de façon intraluminaire le lumen d'une voie de passage du corps, comprenant une greffe ou prothèse vasculaire (70) présentant au moins un organe tubulaire à paroi mince (71), expansible et déformable, comportant des première et seconde extrémités (72,73) et une surface de paroi, disposée entre les première et seconde extrémités (72,73), la surface de paroi présentant une pluralité de fentes (82) formées en son sein, les fentes (82) étant disposées sensiblement parallèlement à l'axe longitudinal desdits organes tubulaires (71), un cathéter (83), présentant une par-

tie (84) expansible, gonflable lui étant associée et comprenant des moyens pour monter et maintenir la prothèse ou greffe vasculaire tubulaire (70) expansible à paroi mince sur la partie expansible gonflable (84), de manière que lors du gonflage de la partie expansible gonflable du cathéter (83), l'organe (71) soit dilaté et déformé radialement vers l'extérieur, mis en contact avec la voie de passage du corps (80), caractérise en ce que le dispositif comprend une pluralité d'organes tubulaires (71) à paroi mince et au moins un connecteur (100) étant disposé entre des organes tubulaires (71) adjacents, pour relier de façon flexible des organes tubulaires (71) adjacents.

6. Dispositif selon la revendication 5, caractérisé en ce que le moyen de montage et de maintien comprend des bagues de maintien (86), disposées sur le cathéter (83), adjacentes à la partie expansible, gonflable (89) et adjacentes aux extrémités des prothèses tubulaires expansibles (70).

Fig.2

Fig.1B

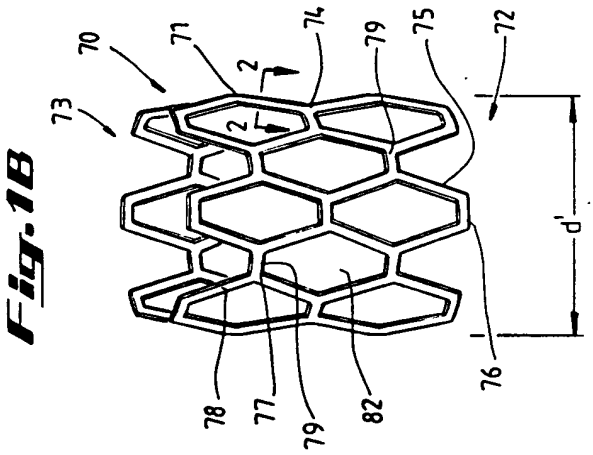


Fig.1A

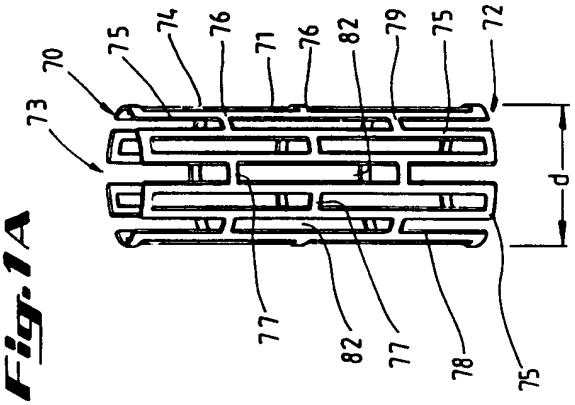
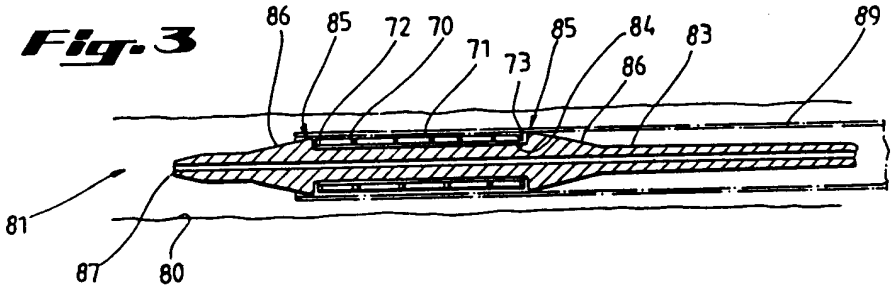


Fig. 3



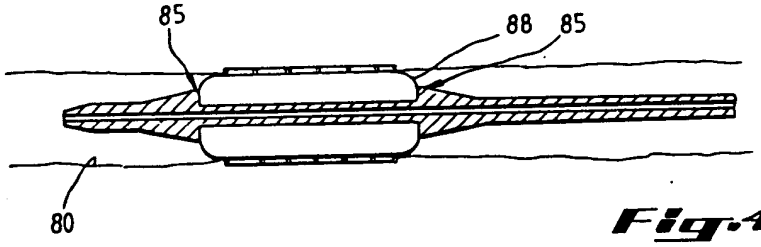
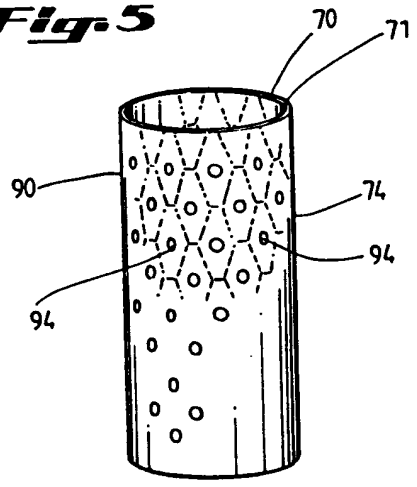


Fig. 4

Fig. 5



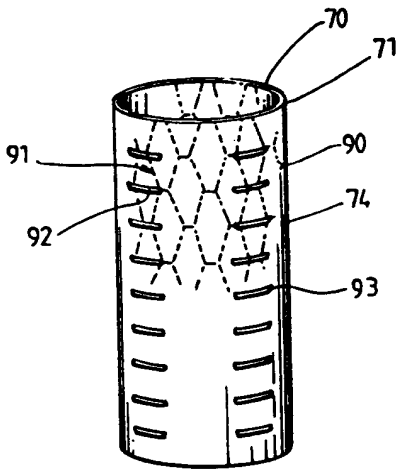


Fig. 6

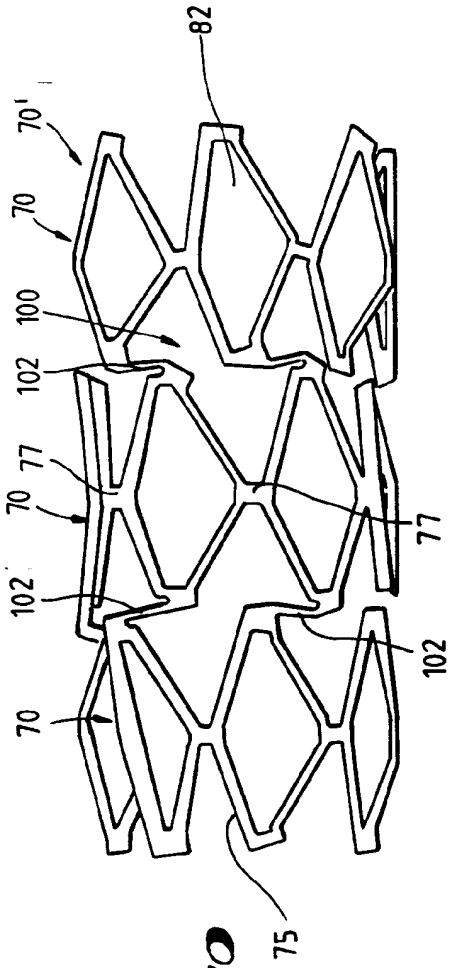


Fig.10

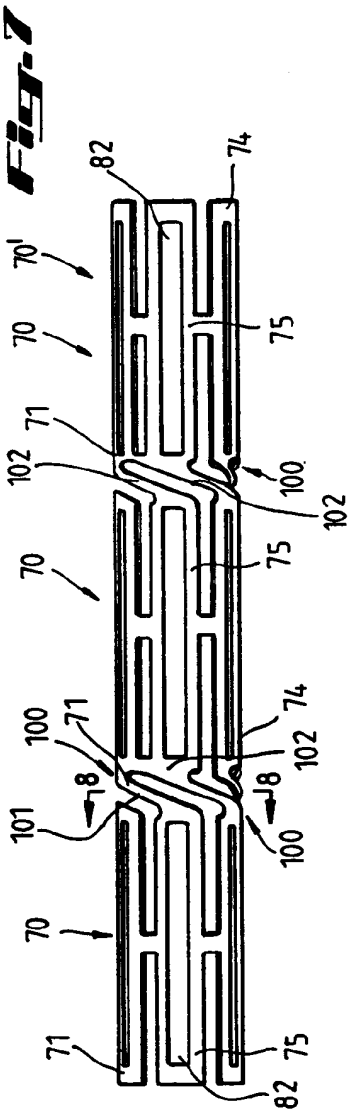


Fig.7

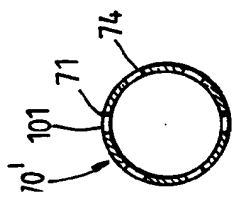


Fig.8

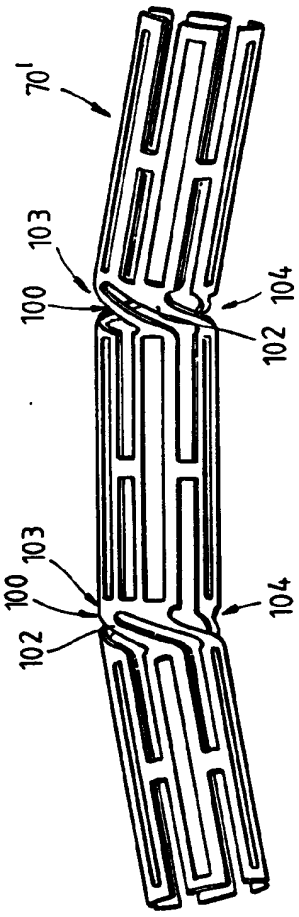


Fig.9